

***SOUTH AMERICAN GELATIN MANUFACTURERS ASSOCIATION –
S A G M A***

Sao Paulo, August 20th , 2004

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockvill, MD 20852

Re: Docket No. 2004N-0257
Recordkeeping Requirement for Human Food and Cosmetics
Manufactured From, Processed With, or Otherwise Containing
Material from Cattle: Proposed Rule (69 Fed. Reg. 42275: July 14, 2004)

Dear Sirs,

The associated members of SAGMA - Southamerican Gelatine Manufacturers' Association - represent approximately 90 % of the Southamerican production of edible and pharmaceutical gelatine, principally manufactured from bovine hide. The major part of this gelatine is successfully exported to many countries throughout the world, due to the fact, that the gelatine originates from member regions which are BSE free or provisionally free of BSE.

In view of the above, SAGMA comments,

that bovine hide gelatine has been scientifically considered as safe and free from any and all potential BSE infectivity associated with cattle material.

The OIE Terrestrial Animal Health Code, does not recommend to restrict the trade of gelatine, regardless of the BSE status of the exporting country or

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zone, for gelatine and collagen coming from hides and skins because these products or tissues have not demonstrated BSE infectivity in cattle.

All rawmaterial used in the member countries of our association for the production of edible and pharmaceutical gelatine derives from healthy animals slaughtered under the supervision of the member country's Veterinary Health Service.

All documentation for trading gelatine, determined, ruled and controlled by the member country's official Authorities is in agreement with international regulations, issued by a.o. the OIE, the EU and innumerous countries and regions which import Southamerican gelatine permitting the traceability of the rawmaterial applicated.

Our industry is making all efforts to produce foodstaff which is free from any risk for human health. We therefore conpile with internationally and scientifically based regulations to ensure the safety of our gelatine. It does not seem reasonable to us to provide further recordkeeping documents for bovine hide based gelatine exported by SAGMA member countries into the US, since the existing internationally recognized regulations and rules for bovine hide gelatine attend all safety considerations on the present scientific status.

We appreciate Your attention.

Best regards

Reiner Quade
Secretary General

Rua Boa Vista, 254 – 7º and. S. 721, São Paulo – SP CEP 01014-907 – Brasil
Telephone: (11) 4612-8111 ou (19) 3666-6000 / Fax (11) 4612-8208 ou (19) 3666-6010

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SAGMA